

AMY W. SCHULMAN
DLA PIPER LLP
1251 Avenue of the Americas
New York, NY 10020
Telephone: (212) 335-4500
Facsimile: (212) 335-4501
amy.schulman@dlapiper.com

STUART M. GORDON (SBN: 037477)
GORDON & REES LLP
Embarcadero Center West
275 Battery Street, Suite 2000
San Francisco, CA 94111
Telephone: (415) 986-5900
Facsimile: (415) 986-8054
sgordon@gordonrees.com

MICHAEL C. ZELLERS (SBN: 146904)
TUCKER ELLIS & WEST LLP
515 South Flower Street, Suite 4200
Los Angeles, CA 90071-2223
Telephone: (213) 430-3400
Facsimile: (213) 430-3409
michael.zellers@tuckerellis.com

Attorneys for Defendants
PFIZER INC., PHARMACIA CORPORATION, AND
G.D. SEARLE LLC

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

1 NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiff's Complaint as
2 "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation ("Pharmacia"), and G.D. Searle LLC
3 ("Searle") (collectively "Defendants"), and file this Answer to Plaintiff's Complaint
4 ("Complaint"), and would respectfully show the Court as follows:

I.

PRELIMINARY STATEMENT

7 The Complaint does not state in sufficient detail when Plaintiff was prescribed or used
8 Bextra® (valdecoxib) (“Bextra®”). Accordingly, this Answer can only be drafted generally.
9 Defendants may seek leave to amend this Answer when discovery reveals the specific time
10 periods in which Plaintiff was prescribed and used Bextra®.

II.

ANSWER

Response to Allegations Regarding Parties

14 1. Defendants admit that Plaintiff brought this civil action seeking monetary damages, but
15 deny that Plaintiff is entitled to any relief or damages. Defendants admit that, during certain
16 periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States
17 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
18 accordance with their approval by the FDA. Defendants admit that, during certain periods of
19 time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed,
20 co-promoted and distributed Bextra® in the United States to be prescribed by healthcare
21 providers who are by law authorized to prescribe drugs in accordance with their approval by the
22 FDA. Defendants state that Bextra® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendants state that the potential effects of
24 Bextra® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage,
27 and deny the remaining allegations in this paragraph of the Complaint.

28 2. Defendants are without knowledge or information sufficient to form a belief as to the

28 2. Defendants are without knowledge or information sufficient to form a belief as to the

1 truth of the allegations regarding Plaintiff's age and citizenship, and, therefore, deny the same.
2 Defendants are without knowledge or information sufficient to form a belief as to the truth of
3 the allegations regarding whether Plaintiff used Bextra® and Plaintiff's medical condition, and,
4 therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the
5 Complaint.

6 3. Defendants admit that Pfizer is a Delaware corporation with its principal place of
7 business in New York. Defendants admit that Pharmacia acquired Searle in 2000 and that, as
8 the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.
9 Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted
10 Bextra® in the United States, including California, to be prescribed by healthcare providers
11 who are by law authorized to prescribe drugs in accordance with their approval by the FDA.
12 Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and
13 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of
14 such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in
15 this paragraph of the Complaint.

16 4. Defendants admit that Searle is a Delaware limited liability company with its principal
17 place of business in Illinois. Defendants admit that, during certain periods of time, Bextra®
18 was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted
19 and distributed Bextra® in the United States to be prescribed by healthcare providers who are
20 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
21 deny the remaining allegations in this paragraph of the Complaint.

22 5. Defendants admit that Pharmacia is a Delaware corporation with its principal place of
23 business in New Jersey. Defendants admit that, during certain periods of time, Pharmacia
24 marketed and co-promoted Bextra® in the United States, including California, to be prescribed
25 by healthcare providers who are by law authorized to prescribe drugs in accordance with their
26 approval by the FDA. Defendants state that Plaintiff's allegations regarding "predecessors in
27 interest" are vague and ambiguous. Defendants are without knowledge or information to form
28 a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 remaining allegations in this Paragraph of the Complaint.

2 **Response to Allegations Regarding Jurisdiction and Venue**

3 6. Defendants are without knowledge or information to form a belief as to the truth of the
4 allegations in this paragraph of the Complaint regarding the amount in controversy, and,
5 therefore, deny that the same. However, Defendants admit that Plaintiff claims that the amount
6 in controversy exceeds \$75,000, exclusive of interests and costs.

7 7. Defendants are without knowledge or information sufficient to form a belief as to the
8 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's citizenship and
9 the amount in controversy, and, therefore, deny the same. However, Defendants admit that
10 Plaintiff claims that the parties are diverse and that the amount in controversy exceeds \$75,000,
11 exclusive of interests and costs.

12 8. Defendants are without knowledge or information sufficient to form a belief as to the
13 truth of the allegations in this paragraph of the Complaint regarding the judicial district in
14 which the asserted claims allegedly arose, and, therefore, deny the same. Defendants deny
15 committing a tort in the State of New Mexico or the State of California and deny the remaining
16 allegations in this paragraph of the Complaint.

17 9. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
18 and co-promoted Bextra® in the United States, including California and Louisiana, to be
19 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
20 with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra®
21 was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted
22 and distributed Bextra® in the United States to be prescribed by healthcare providers who are
23 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
24 admit that they provided FDA-approved prescribing information regarding Bextra®.
25 Defendants admit that they do business in the State of California. Defendants state that
26 Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous.
27 Defendants are without knowledge or information to form a belief as to the truth of such
28 allegations, and, therefore, deny the same. Defendants deny any wrongful conduct and deny the

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 remaining allegations in this paragraph of the Complaint.

2 **Response to Allegations Regarding Interdistrict Assignment**

3 10. Defendants state that this paragraph of the Complaint contains legal contentions to
4 which no response is required. To the extent that a response is deemed required, Defendants
5 admit that this case should be transferred to In re: Bextra and Celebrex Marketing, Sales Prac.
6 and Prods. Liab. Litig., MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial
7 Panel on Multidistrict Litigation on September 6, 2005.

8 **Response to Factual Allegations**

9 11. Defendants are without knowledge or information sufficient to form a belief as to the
10 truth of the allegations regarding Plaintiff's medical condition and whether Plaintiff used
11 Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct, deny that
12 Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph
13 of the Complaint.

14 12. Defendants admit that Bextra® was expected to reach consumers without substantial
15 change from the time of sale. Defendants are without knowledge or information sufficient to
16 form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra® and,
17 therefore, deny the same. Defendants deny the remaining allegations this paragraph of the
18 Complaint.

19 13. Defendants state that Bextra® was and is safe and effective when used in accordance
20 with its FDA-approved prescribing information. Defendants state that the potential effects of
21 Bextra® were and are adequately described in its FDA-approved prescribing information,
22 which was at all times adequate and comported with applicable standards of care and law.
23 Defendants are without knowledge or information sufficient to form a belief as to the truth of
24 the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
25 Defendants deny remaining the allegations in this paragraph of the Complaint.

26 14. Defendants admit that Bextra® is in a class of drugs that is, at times, referred to as non-
27 steroidal anti-inflammatory drugs ("NSAIDS"). Defendants state that Bextra® was and is safe
28 and effective when used in accordance with its FDA-approved prescribing information.

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 Defendants state that the potential effects of Bextra® were and are adequately described in its
2 FDA-approved prescribing information, which was at all times adequate and comported with
3 applicable standards of care and law. Defendants deny the remaining allegations in this
4 paragraph of the Complaint.

5 15. The allegations in this paragraph of the Complaint are not directed toward Defendants
6 and, therefore, no response is required. To the extent a response is deemed required,
7 Defendants state that Plaintiff fails to provide the proper context for the allegations in this
8 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to
9 form a belief as to the truth of such allegations and, therefore, deny the same.

10 16. The allegations in this paragraph of the Complaint are not directed toward Defendants
11 and, therefore, no response is required. To the extent a response is deemed required,
12 Defendants state that Plaintiff fails to provide the proper context for the allegations in this
13 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to
14 form a belief as to the truth of such allegations and, therefore, deny the same.

15 17. The allegations in this paragraph of the Complaint are not directed toward Defendants
16 and, therefore, no response is required. To the extent a response is deemed required,
17 Defendants state that Plaintiff fails to provide the proper context for the allegations in this
18 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to
19 form a belief as to the truth of such allegations and, therefore, deny the same.

20 18. The allegations in this paragraph of the Complaint are not directed toward Defendants
21 and, therefore, no response is required. To the extent a response is deemed required,
22 Defendants state that Plaintiff fails to provide the proper context for the allegations in this
23 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to
24 form a belief as to the truth of such allegations and, therefore, deny the same.

25 19. Plaintiff fails to provide the proper context for the allegations in this paragraph of the
26 Complaint. Defendants lack sufficient information or knowledge to form a belief as to the truth
27 of such allegations and, therefore, deny the same.

28 20. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 vague and ambiguous. Defendants are without knowledge or information to form a belief as to
2 the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful
3 conduct and deny the remaining allegations in this paragraph of the Complaint.

4 21. Plaintiff does not allege having used Celebrex® in this Complaint. Nevertheless,
5 Defendants admit that Celebrex® was launched in the United States in February 1999.
6 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
7 FDA-approved prescribing information. Defendants admit that, during certain periods of time,
8 Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be
9 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
10 with their approval by the FDA. Defendants admit that, during certain periods of time,
11 Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-
12 promoted and distributed Celebrex® in the United States to be prescribed by healthcare
13 providers who are by law authorized to prescribe drugs in accordance with their approval by the
14 FDA. The allegations in this paragraph of the Complaint regarding Merck and Vioxx® are not
15 directed toward Defendants and, therefore, no response is required. To the extent a response is
16 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
17 allegations in this paragraph of the Complaint regarding Merck and Vioxx®. Defendants
18 therefore lack sufficient information or knowledge to form a belief as to the truth of such
19 allegations and, therefore, deny the same. Defendants deny the remaining allegations in this
20 paragraph of the Complaint.

21 22. Defendants admit that the New Drug Application for Bextra® was filed with the FDA
22 on January 15, 2001. Defendants admit, as indicated in the package insert approved by the
23 FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis
24 and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea.
25 Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and
26 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of
27 such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in
28 this paragraph of the Complaint.

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 23. Defendants admit that Bextra® was approved by the FDA on November 16, 2001.
2 Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is
3 indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid
4 arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny the remaining
5 allegations in this paragraph of the Complaint.

6 24. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra®
7 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
8 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny
9 the remaining allegations in this paragraph of the Complaint.

10 25. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra®
11 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
12 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state
13 that Bextra® was and is safe and effective when used in accordance with its FDA-approved
14 prescribing information. Defendants state that the potential effects of Bextra® were and are
15 adequately described in its FDA-approved prescribing information, which at all times was
16 adequate and comported with applicable standards of care and law. Defendants deny the
17 remaining allegations in this paragraph of the Complaint.

18 26. Defendants state that Bextra® was and is safe and effective when used in accordance
19 with its FDA-approved prescribing information. Defendants state that the potential effects of
20 Bextra® were and are adequately described in its FDA-approved prescribing information,
21 which at all times was adequate and comported with applicable standards of care and law.
22 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
23 promoted Bextra® in the United States to be prescribed by healthcare providers who are by law
24 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
25 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which
26 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be
27 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
28 with their approval by the FDA. Defendants state that Plaintiff's allegations regarding

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or
2 information to form a belief as to the truth of such allegations, and, therefore, deny the same.
3 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
4 the Complaint.

5 27. Defendants state that Bextra® was and is safe and effective when used in accordance
6 with its FDA-approved prescribing information. Defendants state that the potential effects of
7 Bextra® were and are adequately described in its FDA-approved prescribing information,
8 which at all times was adequate and comported with applicable standards of care and law.
9 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
10 promoted Bextra® in the United States to be prescribed by healthcare providers who are by law
11 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
12 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which
13 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be
14 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
15 with their approval by the FDA. Defendants deny any wrongful conduct and deny the
16 remaining allegations in this paragraph of the Complaint.

17 28. Defendants state that the referenced article speaks for itself and respectfully refer the
18 Court to the article for its actual language and text. Any attempt to characterize the article is
19 denied. Defendants state that Bextra® was and is safe and effective when used in accordance
20 with its FDA-approved prescribing information. Defendants deny the remaining allegations in
21 this paragraph of the Complaint.

22 29. The allegations in this paragraph of the Complaint are not directed towards Defendants
23 and, therefore, no response is necessary. Should a response be deemed necessary, Defendants
24 state that the referenced article speaks for itself and respectfully refer the Court to the article for
25 its actual language and text. Any attempt to characterize the article is denied. Defendants deny
26 the remaining allegations in this paragraph of the Complaint.

27 30. Defendants admit that the New Drug Application for Bextra® was filed with the FDA
28 on January 15, 2001. Defendants admit that Bextra® was approved by the FDA, on November

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 16, 2001. Defendants deny any wrongful conduct and the remaining allegations in this
2 paragraph of the Complaint.

3 31. Defendants state that Bextra® was and is safe and effective when used in accordance
4 with its FDA-approved prescribing information. Defendants state that the potential effects of
5 Bextra® were and are adequately described in its FDA-approved prescribing information,
6 which at all times was adequate and comported with applicable standards of care and law.
7 Defendants deny the allegations in this paragraph of the Complaint.

8 32. Defendants state that the referenced FDA Talk Paper for Bextra® speaks for itself and
9 respectfully refer the Court to the Talk Paper for its actual language and text. Any attempt to
10 characterize the Talk Paper is denied. Defendants deny the remaining allegations in this
11 paragraph of the Complaint.

12 33. Defendants state that the referenced article speaks for itself and respectfully refer the
13 Court to the article for its actual language and text. Any attempt to characterize the article is
14 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

15 34. Plaintiff fails to provide the proper context for the allegations concerning the “post-drug
16 approval meta-analysis study” in this paragraph of the Complaint. Defendants are without
17 sufficient information to confirm or deny such allegations and, therefore, deny the same.
18 Defendants state that the referenced study speaks for itself and respectfully refer the Court to
19 the study for its actual language and text. Any attempt to characterize the study is denied.
20 Defendants deny the remaining allegations in this paragraph of the Complaint.

21 35. The allegations in this paragraph of the Complaint are not directed towards Defendants
22 and, therefore, no response is necessary. Should a response be deemed necessary, Defendants
23 state that the referenced article speaks for itself and respectfully refer the Court to the article for
24 its actual language and text. Any attempt to characterize the article is denied. Defendants deny
25 the remaining allegations in this paragraph of the Complaint.

26 36. The allegations in this paragraph of the Complaint are not directed towards Defendants
27 and, therefore, no response is necessary. Should a response be deemed necessary, Defendants
28 admit that a Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and Risk

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 Management Advisory Committee was held on February 16-18, 2005. Defendants state that the
2 referenced testimony speaks for itself and respectfully refer the Court to the testimony for its
3 actual language and text. Any attempt to characterize the testimony is denied. Defendants
4 deny the remaining allegations in this paragraph of the Complaint.

5 37. Defendants state that Bextra® was and is safe and effective when used in accordance
6 with its FDA-approved prescribing information. Defendants deny any wrongful conduct and
7 deny the remaining allegations in this paragraph of the Complaint.

8 38. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself
9 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language
10 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.
11 Defendants deny the remaining allegations in this paragraph of the Complaint.

12 39. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself
13 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language
14 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.
15 Defendants deny the remaining allegations in this paragraph of the Complaint.

16 40. Defendants state that Bextra® was and is safe and effective when used in accordance
17 with its FDA-approved prescribing information. Defendants deny the allegations in this
18 paragraph of the Complaint.

19 41. Defendants state that the referenced article speaks for itself and respectfully refer the
20 Court to the article for its actual language and text. Any attempt to characterize the article is
21 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this
22 paragraph of the Complaint.

23 42. The allegations in this paragraph of the Complaint are not directed towards Defendants
24 and, therefore, no response is necessary. Should a response be deemed necessary, Defendants
25 state that the referenced article speaks for itself and respectfully refer the Court to the article for
26 its actual language and text. Any attempt to characterize the article is denied. Defendants deny
27 the remaining allegations in this paragraph of the Complaint.

28 43. Defendants state that Bextra® was and is safe and effective when used in accordance

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 with its FDA-approved prescribing information. Defendants state that the potential effects of
2 Bextra® were and are adequately described in its FDA-approved prescribing information,
3 which was at all times adequate and comported with applicable standards of care and law.
4 Defendants deny the allegations in this paragraph of the Complaint.

5 44. Defendants state that Bextra® was and is safe and effective when used in accordance
6 with its FDA-approved prescribing information. Defendants state that the potential effects of
7 Bextra® were and are adequately described in its FDA-approved prescribing information,
8 which was at all times adequate and comported with applicable standards of care and law.
9 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining
10 allegations in this paragraph of the Complaint.

11 45. Defendants state that Bextra® was and is safe and effective when used in accordance
12 with its FDA-approved prescribing information. Defendants state that the potential effects of
13 Bextra® were and are adequately described in its FDA-approved prescribing information,
14 which was at all times adequate and comported with applicable standards of care and law.
15 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
16 the Complaint.

17 46. Defendants deny the allegations in this paragraph of the Complaint.

18 47. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
19 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
20 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
21 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
22 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
23 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
24 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and
25 effective when used in accordance with its FDA-approved prescribing information. Defendants
26 state that the potential effects of Bextra® were and are adequately described in its FDA-
27 approved prescribing information, which was at all times adequate and comported with
28 applicable standards of care and law. Defendants are without knowledge or information

1 sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used
2 Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct and deny the
3 allegations in this paragraph of the Complaint.

4 48. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
5 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
6 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
7 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
8 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
9 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
10 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and
11 effective when used in accordance with its FDA-approved prescribing information. Defendants
12 state that the potential effects of Bextra® were and are adequately described in its FDA-
13 approved prescribing information, which was at all times adequate and comported with
14 applicable standards of care and law. Defendants deny the remaining allegations in this
15 paragraph of the Complaint.

16 49. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
17 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
18 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
19 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
20 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
21 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
22 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and
23 effective when used in accordance with its FDA-approved prescribing information. Defendants
24 state that the potential effects of Bextra® were and are adequately described in its FDA-
25 approved prescribing information, which was at all times adequate and comported with
26 applicable standards of care and law. Defendants admit, as indicated in the package insert
27 approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms
28 of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 dysmenorrhea. Defendants deny the remaining allegations in this paragraph of the Complaint.
2 50. Defendants state that Bextra® was and is safe and effective when used in accordance
3 with its FDA-approved prescribing information. Defendants state that the potential effects of
4 Bextra® were and are adequately described in its FDA-approved prescribing information,
5 which at all times was adequate and comported with applicable standards of care and law.
6 Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and
7 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of
8 such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny
9 that Bextra® is defective, and deny the allegations in this paragraph of the Complaint.

10 51. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
11 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
12 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
13 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
14 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
15 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
16 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and
17 effective when used in accordance with its FDA-approved prescribing information. Defendants
18 state that the potential effects of Bextra® were and are adequately described in its FDA-
19 approved prescribing information, which was at all times adequate and comported with
20 applicable standards of care and law. Defendants deny the remaining allegations in this
21 paragraph of the Complaint.

22 52. Defendants state that Bextra® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendants state that the potential effects of
24 Bextra® were and are adequately described in its FDA-approved prescribing information,
25 which at all times was adequate and comported with applicable standards of care and law.
26 Defendants deny the remaining allegations in this paragraph of the Complaint.

27 53. Defendants state that Bextra® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 Bextra® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
4 the Complaint.

5 54. Defendants state that Bextra® was and is safe and effective when used in accordance
6 with its FDA-approved prescribing information. Defendants state that the potential effects of
7 Bextra® were and are adequately described in its FDA-approved prescribing information,
8 which was at all times adequate and comported with applicable standards of care and law.
9 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
10 the Complaint.

11 55. Defendants deny the allegations in this paragraph of the Complaint.

12 56. Defendants admit that the sale of Bextra® was voluntarily suspended in the U.S. market
13 as of April 7, 2005. Defendants deny any wrongful conduct and deny the remaining allegations
14 contained in this paragraph of the Complaint.

15 57. Defendants state that Bextra® was and is safe and effective when used in accordance
16 with its FDA-approved prescribing information. Defendants state that the potential effects of
17 Bextra® were and are adequately described in its FDA-approved prescribing information,
18 which was at all times adequate and comported with applicable standards of care and law.
19 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining
20 allegations in this paragraph of the Complaint.

21 58. Defendants state that Bextra® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendants state that the potential effects of
23 Bextra® were and are adequately described in its FDA-approved prescribing information,
24 which was at all times adequate and comported with applicable standards of care and law.
25 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
26 the Complaint.

27 59. Defendants deny any wrongful conduct and deny the remaining allegations in this
28 paragraph of the Complaint.

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 60. Defendants state that Bextra® was and is safe and effective when used in accordance
2 with its FDA-approved prescribing information. Defendants state that the potential effects of
3 Bextra® were and are adequately described in its FDA-approved prescribing information,
4 which was at all times adequate and comported with applicable standards of care and law.
5 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
6 promoted Bextra® in the United States to be prescribed by healthcare providers who are by law
7 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
8 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which
9 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be
10 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
11 with their approval by the FDA. Defendants deny any wrongful conduct and deny the
12 remaining allegations in this paragraph of the Complaint.

13 61. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
14 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
15 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
16 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
17 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
18 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
19 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
20 paragraph of the Complaint.

21 62. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
22 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
23 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
24 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
25 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
26 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
27 accordance with their approval by the FDA. Defendants admit, as indicated in the package
28 insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of
2 primary dysmenorrhea. Defendants deny any wrongful conduct and deny the remaining
3 allegations in this paragraph of the Complaint.

4 63. Defendants state that Bextra® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendants state that the potential effects of
6 Bextra® were and are adequately described in its FDA-approved prescribing information,
7 which was at all times adequate and comported with applicable standards of care and law.
8 Defendants are without knowledge or information sufficient to form a belief as to the truth of
9 the allegations regarding and whether Plaintiff used Bextra® and, therefore, deny the same.
10 Defendants deny any wrongful conduct, deny that Bextra® is defective, deny that Bextra®
11 caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the
12 Complaint.

13 64. Defendants state that Bextra® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants state that the potential effects of
15 Bextra® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants are without knowledge or information sufficient to form a belief as to the truth of
18 the allegations regarding and whether Plaintiff used Bextra® and, therefore, deny the same.
19 Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and
20 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of
21 such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny
22 that Bextra® is defective, deny that Bextra® caused Plaintiff injury or damage, and deny the
23 remaining allegations in this paragraph of the Complaint.

24 **Response to First Cause of Action: Negligence**

25 65. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
26 Complaint as if fully set forth herein.

27 66. Defendants state that this paragraph of the Complaint contains legal contentions to
28 which no response is deemed required. To the extent a response is deemed required,

1 Defendants admit that they had duties as are imposed by law but deny having breached such
2 duties. Defendants state that the potential effects of Bextra® were and are adequately described
3 in its FDA-approved prescribing information, which was at all times adequate and comported
4 with applicable standards of care and law. Defendants state that Bextra® was and is safe and
5 effective when used in accordance with its FDA-approved prescribing information. Defendants
6 deny the remaining allegations in this paragraph of the Complaint.

7 67. Defendants state that this paragraph of the Complaint contains legal contentions to
8 which no response is deemed required. To the extent a response is deemed required,
9 Defendants admit that they had duties as are imposed by law but deny having breached such
10 duties. Defendants state that Bextra® was and is safe and effective when used in accordance
11 with its FDA-approved prescribing information. Defendants deny the remaining allegations in
12 this paragraph of the Complaint.

13 68. Defendants state that this paragraph of the Complaint contains legal contentions to
14 which no response is required. To the extent that a response is deemed required, Defendants
15 admit that they had duties as are imposed by law but deny having breached such duties.
16 Defendants state that Bextra® was and is safe and effective when used in accordance with its
17 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
18 were and are adequately described in its FDA-approved prescribing information, which was at
19 all times adequate and comported with applicable standards of care and law. Defendants deny
20 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint,
21 including all subparts.

22 69. Defendants state that Bextra® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendants state that the potential effects of
24 Bextra® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendants are without knowledge or information sufficient to form a belief as to the truth of
27 the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
28 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 the Complaint.

2 70. Defendants state that Bextra® was and is safe and effective when used in accordance
3 with its FDA-approved prescribing information. Defendants state that the potential effects of
4 Bextra® were and are adequately described in its FDA-approved prescribing information,
5 which was at all times adequate and comported with applicable standards of care and law.
6 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
7 the Complaint.

8 71. Defendants state that Bextra® was and is safe and effective when used in accordance
9 with its FDA-approved prescribing information. Defendants deny any wrongful conduct, deny
10 that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this
11 paragraph of the Complaint.

12 72. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
13 damage, and deny the remaining allegations in this paragraph of the Complaint.

14 73. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
15 damage and deny the remaining allegations in this paragraph of the Complaint.

16 74. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
17 damage, and deny the remaining allegations in this paragraph of the Complaint.

18 **Response to Second Cause of Action: Strict Liability**

19 75. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
20 Complaint as if fully set forth herein.

21 76. Defendants are without knowledge or information sufficient to form a belief as to the
22 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
23 Defendants admit that Bextra® was expected to reach consumers without substantial change in
24 the condition from the time of sale. Defendants admit that, during certain periods of time,
25 Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed
26 by healthcare providers who are by law authorized to prescribe drugs in accordance with their
27 approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was
28 manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and

1 distributed Bextra® in the United States to be prescribed by healthcare providers who are by
2 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
3 state that Bextra® was and is safe and effective when used in accordance with its FDA-
4 approved prescribing information. Defendants state that the potential effects of Bextra® were
5 and are adequately described in its FDA-approved prescribing information, which was at all
6 times adequate and comported with applicable standards of care and law. Defendants deny the
7 remaining allegations in this paragraph of the Complaint.

8 77. Defendants state that Bextra® was and is safe and effective when used in accordance
9 with its FDA-approved prescribing information. Defendants state that the potential effects of
10 Bextra® were and are adequately described in its FDA-approved prescribing information,
11 which was at all times adequate and comported with applicable standards of care and law.
12 Defendants deny the allegations in this paragraph of the Complaint.

13 78. Defendants state that Bextra® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants state that the potential effects of
15 Bextra® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants deny that Bextra® is defective or unreasonably dangerous, and deny the remaining
18 allegations in this paragraph of the Complaint.

19 79. Defendants state that this paragraph of the Complaint contains legal contentions to
20 which no response is deemed required. To the extent a response is deemed required,
21 Defendants state that Bextra® was and is safe and effective when used in accordance with its
22 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
23 were and are adequately described in its FDA-approved prescribing information, which was at
24 all times adequate and comported with applicable standards of care and law. Defendants deny
25 that Bextra® is unreasonably dangerous, and deny the remaining allegations in this paragraph
26 of the Complaint, including all subparts.

27 80. Defendants state that this paragraph of the Complaint contains legal contentions to
28 which no response is deemed required. To the extent a response is deemed required,

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 Defendants state that Bextra® was and is safe and effective when used in accordance with its
2 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
3 were and are adequately described in its FDA-approved prescribing information, which was at
4 all times adequate and comported with applicable standards of care and law. Defendants deny
5 any wrongful conduct, deny that Bextra® is unreasonably dangerous, and deny the remaining
6 allegations in this paragraph of the Complaint.

7 81. Defendants state that Bextra® was and is safe and effective when used in accordance
8 with its FDA-approved prescribing information. Defendants state that the potential effects of
9 Bextra® were and are adequately described in its FDA-approved prescribing information,
10 which was at all times adequate and comported with applicable standards of care and law.
11 Defendants deny any wrongful conduct, deny that Bextra® is defective, deny that Bextra®
12 caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the
13 Complaint.

14 82. Defendants state that Bextra® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendants state that the potential effects of
16 Bextra® were and are adequately described in its FDA-approved prescribing information,
17 which was at all times adequate and comported with applicable standards of care and law.
18 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining
19 allegations in this paragraph of the Complaint.

20 83. Defendants are without knowledge or information sufficient to form a belief as to the
21 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
22 Defendants state that Bextra® was and is safe and effective when used in accordance with its
23 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
24 were and are adequately described in its FDA-approved prescribing information, which was at
25 all times adequate and comported with applicable standards of care and law. Defendants admit
26 that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra®
27 in the United States to be prescribed by healthcare providers who are by law authorized to
28 prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 certain periods of time, Bextra® was manufactured and packaged for Searle, which developed,
2 tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by
3 healthcare providers who are by law authorized to prescribe drugs in accordance with their
4 approval by the FDA. Defendants deny any wrongful conduct, deny that Bextra® is defective,
5 deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this
6 paragraph of the Complaint.

7 84. Defendants state that Bextra® was and is safe and effective when used in accordance
8 with its FDA-approved prescribing information. Defendants state that the potential effects of
9 Bextra® were and are adequately described in its FDA-approved prescribing information,
10 which was at all times adequate and comported with applicable standards of care and law.
11 Defendants deny the remaining allegations in this paragraph of the Complaint.

12 85. Defendants are without knowledge or information sufficient to form a belief as to the
13 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
14 Defendants state that Bextra® was and is safe and effective when used in accordance with its
15 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
16 were and are adequately described in its FDA-approved prescribing information, which was at
17 all times adequate and comported with applicable standards of care and law. Defendants deny
18 the remaining allegations in this paragraph of the Complaint.

19 86. Defendants state that Bextra® was and is safe and effective when used in accordance
20 with its FDA-approved prescribing information. Defendants deny any wrongful conduct and
21 deny the remaining allegations in this paragraph of the Complaint.

22 87. Defendants are without knowledge or information sufficient to form a belief as to the
23 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
24 Defendants state that Bextra® was and is safe and effective when used in accordance with its
25 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
26 were and are adequately described in its FDA-approved prescribing information, which was at
27 all times adequate and comported with applicable standards of care and law. Defendants deny
28 that Bextra® is defective and deny the remaining allegations in this paragraph of the Complaint.

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 88. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
2 damage, and deny the remaining allegations in this paragraph of the Complaint.

3 89. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
4 damage, and deny the remaining allegations in this paragraph of the Complaint.

5 90. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
6 damage, and deny the remaining allegations in this paragraph of the Complaint.

7 **Response to Third Cause of Action: Breach of Express Warranty**

8 91. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
9 Complaint as if fully set forth herein.

10 92. Defendants are without knowledge or information sufficient to form a belief as to the
11 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.

12 Defendants state that Bextra® was and is safe and effective when used in accordance with its
13 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
14 were and are adequately described in its FDA-approved prescribing information, which was at
15 all times adequate and comported with applicable standards of care and law. Defendants admit
16 that they provided FDA-approved prescribing information regarding Bextra®. Defendants
17 deny the remaining allegations in this paragraph of the Complaint.

18 93. Defendants are without knowledge or information sufficient to form a belief as to the
19 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.

20 Defendants state that Bextra® was and is safe and effective when used in accordance with its
21 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
22 were and are adequately described in its FDA-approved prescribing information, which was at
23 all times adequate and comported with applicable standards of care and law. Defendants admit
24 that they provided FDA-approved prescribing information regarding Bextra®. Defendants
25 deny the remaining allegations in this paragraph of the Complaint, including all subparts.

26 94. Defendants deny the allegations in this paragraph of the Complaint.

27 95. Defendants state that Bextra® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 Bextra® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants admit that they provided FDA-approved prescribing information regarding
4 Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

5 96. Defendants state that Bextra® was and is safe and effective when used in accordance
6 with its FDA-approved prescribing information. Defendants state that the potential effects of
7 Bextra® were and are adequately described in its FDA-approved prescribing information,
8 which was at all times adequate and comported with applicable standards of care and law.
9 Defendants admit that they provided FDA-approved prescribing information regarding
10 Bextra®. Defendants deny any wrongful conduct the remaining allegations in this paragraph of
11 the Complaint.

12 97. Defendants are without knowledge or information sufficient to form a belief as to the
13 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
14 Defendants admit that they provided FDA-approved prescribing information regarding
15 Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

16 98. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
17 damage, and deny the remaining allegations in this paragraph of the Complaint.

18 99. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
19 damage, and deny the remaining allegations in this paragraph of the Complaint.

20 100. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
21 damage, and deny the remaining allegations in this paragraph of the Complaint.

22 **Response to Fourth Cause of Action: Breach of Implied Warranty**

23 101. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
24 Complaint as if fully set forth herein.

25 102. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
26 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
27 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
28 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
2 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
3 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
4 paragraph of the Complaint.

5 103. Defendants admit that they provided FDA-approved prescribing information regarding
6 Bextra®. Defendants admit, as indicated in the package insert approved by the FDA, that
7 Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
8 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state
9 that Bextra® was and is safe and effective when used in accordance with its FDA-approved
10 prescribing information. Defendants deny the remaining allegations in this paragraph of the
11 Complaint.

12 104. Defendants are without knowledge or information sufficient to form a belief as to the
13 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
14 Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is
15 indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid
16 arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny the remaining
17 allegations in this paragraph of the Complaint.

18 105. Defendants are without knowledge or information sufficient to form a belief as to the
19 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
20 Defendants state that Bextra® was and is safe and effective when used in accordance with its
21 FDA-approved prescribing information. Defendants deny the remaining allegations in this
22 paragraph of the Complaint.

23 106. Defendants are without knowledge or information sufficient to form a belief as to the
24 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
25 Defendants state that Bextra® was expected to reach consumers without substantial change in
26 the condition from the time of sale. Defendants deny the remaining allegations in this
27 paragraph of the Complaint.

28 107. Defendants are without knowledge or information sufficient to form a belief as to the

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
 2 Defendants state that Bextra® was and is safe and effective when used in accordance with its
 3 FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the
 4 remaining allegations in this paragraph of the Complaint.

5 108. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
 6 damage, and deny the remaining allegations in this paragraph of the Complaint.

7 109. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
 8 damage, and deny the remaining allegations in this paragraph of the Complaint.

9 110. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
 10 damage, and deny the remaining allegations in this paragraph of the Complaint.

11 **Response to Fifth Cause of Action: Fraudulent Misrepresentation & Concealment**

12 111. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
 13 Complaint as if fully set forth herein.

14 112. Defendants state that this paragraph of the Complaint contains legal contentions to
 15 which no response is deemed required. To the extent a response is deemed required,
 16 Defendants admit that they had duties as are imposed by law but deny having breached such
 17 duties. Defendants state that Bextra® was and is safe and effective when used in accordance
 18 with its FDA-approved prescribing information. Defendants state that the potential effects of
 19 Bextra® were and are adequately described in its FDA-approved prescribing information,
 20 which was at all times adequate and comported with applicable standards of care and law.
 21 Defendants deny the remaining allegations in this paragraph of the Complaint.

22 113. Defendants state that Bextra® was and is safe and effective when used in accordance
 23 with its FDA-approved prescribing information. Defendants state that the potential effects of
 24 Bextra® were and are adequately described in its FDA-approved prescribing information,
 25 which was at all times adequate and comported with applicable standards of care and law.
 26 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
 27 the Complaint, including all subparts.

28 114. Defendants state that Bextra® was and is safe and effective when used in accordance

1 with its FDA-approved prescribing information. Defendants state that the potential effects of
2 Bextra® were and are adequately described in its FDA-approved prescribing information,
3 which was at all times adequate and comported with applicable standards of care and law.
4 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
5 the Complaint.

6 115. Defendants state that Bextra® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendants state that the potential effects of
8 Bextra® were and are adequately described in its FDA-approved prescribing information,
9 which was at all times adequate and comported with applicable standards of care and law.
10 Defendants deny any wrongful conduct, deny that Bextra® is defective or unreasonably
11 dangerous, and deny the remaining allegations in this paragraph of the Complaint.

12 116. Defendants state that Bextra® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendants state that the potential effects of
14 Bextra® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
17 the Complaint.

18 117. Defendants deny any wrongful conduct and deny the remaining allegations in this
19 paragraph of the Complaint.

20 118. Defendants are without knowledge or information sufficient to form a belief as to the
21 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
22 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
23 the Complaint.

24 119. Defendants are without knowledge or information sufficient to form a belief as to the
25 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
26 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
27 the Complaint.

28 120. Defendants are without knowledge or information sufficient to form a belief as to the

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
2 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
3 the Complaint.

4 121. Defendants deny any wrongful conduct and deny the remaining allegations in this
5 paragraph of the Complaint.

6 122. Defendants are without knowledge or information sufficient to form a belief as to the
7 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
8 Defendants state that Bextra® was and is safe and effective when used in accordance with its
9 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
10 were and are adequately described in its FDA-approved prescribing information, which was at
11 all times adequate and comported with applicable standards of care and law. Defendants deny
12 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

13 123. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
14 damage, and deny the remaining allegations in this paragraph of the Complaint.

15 124. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
16 damage, and deny the remaining allegations in this paragraph of the Complaint.

17 125. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
18 damage, and deny the remaining allegations in this paragraph of the Complaint.

19 **Response to Sixth Cause of Action: Unjust Enrichment**

20 126. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
21 Complaint as if fully set forth herein.

22 127. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
23 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
24 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
25 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
26 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
27 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
28 accordance with their approval by the FDA. Defendants deny the remaining allegations in this

1 paragraph of the Complaint.

2 128. Defendants are without knowledge or information sufficient to form a belief as to the
3 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
4 Defendants deny the remaining allegations in this paragraph of the Complaint.

5 129. Defendants are without knowledge or information sufficient to form a belief as to the
6 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
7 Defendants deny the remaining allegations in this paragraph of the Complaint.

8 130. Defendants are without knowledge or information sufficient to form a belief as to the
9 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
10 Defendants state that Bextra® was and is safe and effective when used in accordance with its
11 FDA-approved prescribing information. Defendants deny the remaining allegations in this
12 paragraph of the Complaint.

13 131. Defendants are without knowledge or information sufficient to form a belief as to the
14 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
15 Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage,
16 and deny the remaining allegations in this paragraph of the Complaint.

17 132. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
18 damage, and deny the remaining allegations in this paragraph of the Complaint.

19 **Response to Seventh Cause of Action: Unjust Enrichment**

20 133. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
21 Complaint as if fully set forth herein.

22 134. Defendants state that this paragraph of the Complaint contains legal contentions to
23 which no response is required. To the extent that a response is deemed required, Defendants
24 admit that they had duties as are imposed by law but deny having breached such duties.
25 Defendants deny the remaining allegations in this paragraph of the Complaint.

26 135. Defendants are without knowledge or information sufficient to form a belief as to the
27 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
28 Defendants state that Bextra® was and is safe and effective when used in accordance with its

1 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
2 were and are adequately described in its FDA-approved prescribing information, which was at
3 all times adequate and comported with applicable standards of care and law. Defendants deny
4 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

5 136. Defendants are without knowledge or information sufficient to form a belief as to the
6 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
7 Defendants state that Bextra® was and is safe and effective when used in accordance with its
8 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
9 were and are adequately described in its FDA-approved prescribing information, which was at
10 all times adequate and comported with applicable standards of care and law. Defendants deny
11 any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the
12 remaining allegations in this paragraph of the Complaint.

13 137. Defendants are without knowledge or information sufficient to form a belief as to the
14 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
15 Defendants deny the remaining allegations in this paragraph of the Complaint.

16 138. Defendants are without knowledge or information sufficient to form a belief as to the
17 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
18 Defendants state that Bextra® was and is safe and effective when used in accordance with its
19 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
20 were and are adequately described in its FDA-approved prescribing information, which was at
21 all times adequate and comported with applicable standards of care and law. Defendants deny
22 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

23 139. Defendants state that this paragraph of the Complaint contains legal contentions to
24 which no response is required. To the extent that a response is deemed required, Defendants
25 deny any wrongful conduct and deny the remaining allegations in this paragraph of the
26 Complaint.

27 140. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
28 damage, and deny the remaining allegations in this paragraph of the Complaint.

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 141. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
 2 damage, and deny the remaining allegations in this paragraph of the Complaint.

3 142. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
 4 damage, and deny the remaining allegations in this paragraph of the Complaint.

5 143. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
 6 damage, and deny the remaining allegations in this paragraph of the Complaint.

7 **Response to Prayer for Relief**

8 Answering the unnumbered paragraph of the Complaint headed "Prayer for Relief,"
 9 Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage,
 10 and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

11 **III.**

12 **GENERAL DENIAL**

13 Defendants deny all allegations and/or legal conclusions set forth in Plaintiff's
 14 Complaint that have not been previously admitted, denied, or explained.

15 **IV.**

16 **AFFIRMATIVE DEFENSES**

17 Defendants reserve the right to rely upon any of the following or additional defenses to
 18 claims asserted by Plaintiff to the extent that such defenses are supported by information
 19 developed through discovery or evidence at trial. Defendants affirmatively show that:

20 **First Defense**

21 1. The Complaint fails to state a claim upon which relief can be granted.

22 **Second Defense**

23 2. Bextra® is a prescription medical product. The federal government has preempted the
 24 field of law applicable to the labeling and warning of prescription medical products.
 25 Defendants' labeling and warning of Bextra® was at all times in compliance with applicable
 26 federal law. Plaintiff's causes of action against Defendants, therefore, fail to state a claim upon
 27 which relief can be granted; such claims, if allowed, would conflict with applicable federal law
 28 and violate the Supremacy Clause of the United States Constitution.

Third Defense

3. At all relevant times, Defendants provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

Fourth Defense

4. At all relevant times, Defendants' warnings and instructions with respect to the use of Bextra® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

Fifth Defense

5. Plaintiff's action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

Sixth Defense

6. Plaintiff's action is barred by the statute of repose.

Seventh Defense

7. If Plaintiff sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same were caused by the negligence or fault of the Plaintiff and Plaintiff's damages, if any, are barred or reduced by the doctrines of comparative fault and contributory negligence and by the failure to mitigate damages.

Eighth Defense

8. The proximate cause of the loss complained of by Plaintiff is not due to any acts or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not liable in any way.

Ninth Defense

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendants cannot be liable.

Tenth Defense

10. Any injuries or expenses incurred by Plaintiff were not caused by Bextra®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

Eleventh Defense

11. Defendants affirmatively deny that they violated any duty owed to Plaintiff.

Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a "learned intermediary" in determining the use of the product. Bextra® is a prescription medical product, available only on the order of a licensed physician. Bextra® provided an adequate warning to Plaintiff's treating and prescribing physicians.

Thirteenth Defense

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

Fourteenth Defense

14. Bextra® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Bextra® at the time of the occurrence of the injuries alleged by Plaintiff were legally adequate for its approved usages.

Fifteenth Defense

15. Plaintiff's causes of action are barred in whole or in part by the lack of a defect as the Bextra® allegedly ingested by Plaintiff was prepared in accordance with the applicable standard of care.

Sixteenth Defense

16. If Plaintiff sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same were caused by the unforeseeable alteration, change, improper handling,

1 abnormal use, or other unforeseeable misuse of Bextra® by persons other than Defendants or
2 persons acting on its behalf after the product left the control of Defendants.

3 **Seventeenth Defense**

4 17. Plaintiff's alleged damages were not caused by any failure to warn on the part of
5 Defendants.

6 **Eighteenth Defense**

7 18. Plaintiff's alleged injuries/damages, if any, were the result of preexisting or subsequent
8 conditions unrelated to Bextra®.

9 **Nineteenth Defense**

10 19. Plaintiff knew or should have known of any risk associated with Bextra®; therefore, the
11 doctrine of assumption of the risk bars or diminishes any recovery.

12 **Twentieth Defense**

13 20. Plaintiff is barred from recovering against Defendants because Plaintiff's claims are
14 preempted in accordance with the Supremacy Clause of the United States Constitution and by
15 the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

16 **Twenty-first Defense**

17 21. Plaintiff's claims are barred in whole or in part under the applicable state law because
18 the subject pharmaceutical product at issue was subject to and received pre-market approval by
19 the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

20 **Twenty-second Defense**

21 22. The manufacture, distribution and sale of the pharmaceutical product referred to in
22 Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes,
23 and Plaintiff's causes of action are preempted.

24 **Twenty-third Defense**

25 23. Plaintiff's claims are barred in whole or in part by the deference given to the primary
26 jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at
27 issue under applicable federal laws, regulations, and rules.

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

Twenty-fourth Defense

24. Plaintiff's claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiff's claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Bextra® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-eighth Defense

28. Plaintiff's claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. The imposition of punitive damages in this case would violate Defendants' rights to procedural due process under the Fourteenth Amendment of the United States Constitution, the Constitution of the State of New Mexico, and the Constitution of the State of California, and would additionally violate Defendants' right to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-first Defense

31. Plaintiff's claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution.

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-third Defense

33. Plaintiff's punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

Thirty-fifth Defense

35. Plaintiff failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth

1 Amendment of the United States Constitution, the Commerce Clause of the United States
2 Constitution, and the Full Faith and Credit Clause of the United States Constitution and the
3 Constitutions of the States of New Mexico and California. Any law, statute, or other authority
4 purporting to permit the recovery of punitive damages in this case is unconstitutional, facially
5 and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient
6 standards to guide and restrain the jury's discretion in determining whether to award punitive
7 damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate
8 advance notice as to what conduct will result in punitive damages; (3) permits recovery of
9 punitive damages based on out-of-state conduct, conduct that complied with applicable law, or
10 conduct that was not directed, or did not proximately cause harm, to Plaintiff; (4) permits
11 recovery of punitive damages in an amount that is not both reasonable and proportionate to the
12 amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any; (5)
13 permits jury consideration of net worth or other financial information relating to Defendants;
14 (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict
15 review of any punitive damages awards; (7) lacks constitutionally sufficient standards for
16 appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court
17 precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1, 111
18 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North*
19 *America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*,
20 538 U.S. 408 (2003).

21 **Thirty-ninth Defense**

22 39. The methods, standards, and techniques utilized with respect to the manufacture, design,
23 and marketing of Bextra®, if any, used in this case, included adequate warnings and
24 instructions with respect to the product's use in the package insert and other literature, and
25 conformed to the generally recognized, reasonably available, and reliable state of the
26 knowledge at the time the product was marketed.

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

Fortieth Defense

40. The claims asserted in the Complaint are barred because Bextra® was designed, tested, manufactured and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

Forty-first Defense

41. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendants and over whom Defendants had no control and for whom Defendants may not be held accountable.

Forty-second Defense

42. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

Forty-third Defense

43. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

Forty-fourth Defense

44. Plaintiff's claims are barred because Plaintiff's injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff, and were independent of or far removed from Defendants' conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® did not proximately cause injuries or damages to Plaintiff.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff did not incur any ascertainable loss as a result of Defendants' conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Plaintiff would have taken Bextra® even if the product labeling contained the information that Plaintiff contends should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Bextra® outweighed its risks.

Fiftieth Defense

50. Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources.

Fifty-first Defense

51. Defendants' liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiff.

Fifty-second Defense

52. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-third Defense

53. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act

1 ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiff's
 2 claims conflict with the FDCA, with the regulations promulgated by FDA to implement the
 3 FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations,
 4 and with the specific determinations by FDA specifying the language that should be used in the
 5 labeling accompanying Bextra®. Accordingly, Plaintiff's claims are preempted by the
 6 Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the
 7 United States.

8 **Fifty-fourth Defense**

9 54. Plaintiff's misrepresentation allegations are not stated with the degree of particularity
 10 required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

11 **Fifty-fifth Defense**

12 55. Defendants state on information and belief that the Complaint and each purported cause
 13 of action contained therein is barred by the statutes of limitations contained in California Code
 14 of Civil Procedure §§ 335.1 and 338 and former § 340(3), such other statutes of limitation as
 15 may apply.

16 **Fifty-sixth Defense**

17 56. Defendants state on information and belief that any injuries, losses, or damages suffered
 18 by Plaintiff were proximately caused, in whole or in part, by the negligence or other actionable
 19 conduct of persons or entities other than Defendants. Therefore, Plaintiff's recovery against
 20 Defendants, if any, should be reduced pursuant to California Civil Code § 1431.2.

21 **Fifty-seventh Defense**

22 57. To the extent that Plaintiff seeks punitive damages for an alleged act or omission of
 23 Defendants, no act or omission was oppressive, fraudulent, or malicious under California Civil
 24 Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive
 25 damages is also barred under California Civil Code § 3294(b).

26 **Fifty-eighth Defense**

27 58. Plaintiff has failed to allege conduct warranting imposition of punitive damages under
 28 New Mexico law.

Gordon & Rees, LLP
 275 Battery Street, Suite 2000
 San Francisco, CA 94111

Fifty-ninth Defense

59. The standards in New Mexico governing the award and review of damages for non-pecuniary damages, including damages for mental anguish and pain and suffering, are impermissibly vague or simply non-existent, and are inadequate to ensure that such awards do not include amounts intended as exemplary damages, which are impermissible in a compensatory damages award.

Sixtieth Defense

60. Plaintiff's claims for non-pecuniary damages are unconstitutionally vague and/or overbroad, and are in contravention of Defendant's rights under various provisions of the New Mexico Constitution, including but not limited to Art. II §§ 4, 13, 15, 18, and 19.

Sixty-first Defense

61. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiff's claims.

V.

PRAYER

WHEREFORE, Defendants pray for judgment as follows:

1. That Plaintiff take nothing from Defendants by reason of the Complaint;
2. That the Complaint be dismissed;
3. That Defendants be awarded their costs for this lawsuit;
4. That the trier of fact determine what percentage of the combined fault or other liability of all persons whose fault or other liability proximately caused Plaintiff's alleged injuries, losses or damages is attributable to each person;
5. That any judgment for damages against Defendants in favor of Plaintiff be no greater than an amount which equals their proportionate share, if any, of the total fault or other liability which proximately caused Plaintiff's injuries and damages; and
6. That Defendants have such other and further relief as the Court deems appropriate.

1 September 19, 2007

GORDON & REES LLP

2 By: _____/s/

3 Stuart M. Gordon
4 sgordon@gordonrees.com
5 Embarcadero Center West
6 275 Battery Street, 20th Floor
7 San Francisco, CA 94111
8 Telephone: (415) 986-5900
9 Fax: (415) 986-8054

10 September 19, 2007

TUCKER ELLIS & WEST LLP

11 By: _____/s/

12 Michael C. Zellers
13 michael.zellers@tuckerellis.com
14 515 South Flower Street, Suite 4200
15 Los Angeles, CA 90071-2223
16 Telephone: (213) 430-3400
17 Fax: (213) 430-3409

18 Attorneys for Defendants
19 PFIZER INC., PHARMACIA
20 CORPORATION, AND G.D. SEARLE
21 LLC

22 Gordon & Rees, LLP
23 275 Battery Street, Suite 2000
24 San Francisco, CA 94111

1 **JURY DEMAND**

2 Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC, hereby demand a
3 trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil
4 Procedure.

5 September 19, 2007

GORDON & REES LLP

6
7 By: _____/s/
8 Stuart M. Gordon
9 sgordon@gordonrees.com
10 Embarcadero Center West
11 275 Battery Street, 20th Floor
12 San Francisco, CA 94111
13 Telephone: (415) 986-5900
14 Fax: (415) 986-8054

15 September 19, 2007

TUCKER ELLIS & WEST LLP

16
17 By: _____/s/
18 Michael C. Zellers
19 michael.zellers@tuckerellis.com
20 515 South Flower Street, Suite 4200
21 Los Angeles, CA 90071-2223
22 Telephone: (213) 430-3400
23 Fax: (213) 430-3409

24
25 Attorneys for Defendants
26 PFIZER INC., PHARMACIA
27 CORPORATION, AND G.D. SEARLE
28 LLC

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111